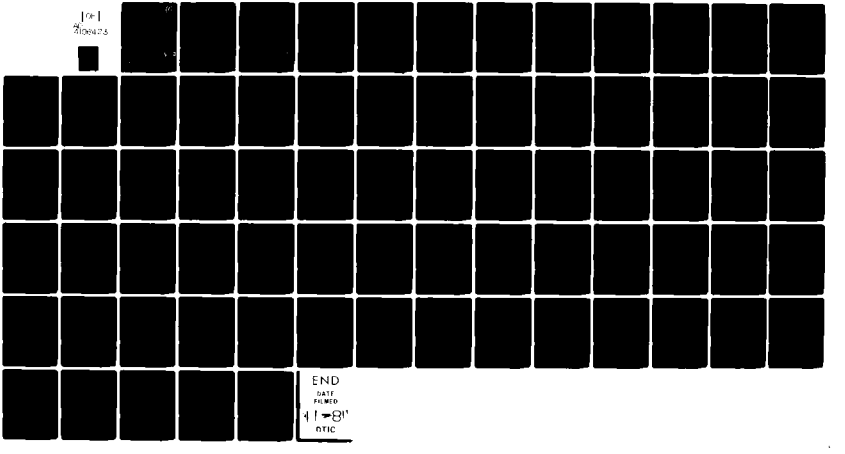
AD-A106 423 AIR FORCE INST OF TECH WRIGHT-PATTERSON AFB OH F/G 6/10
A COMPARISON OF THE APPROACHES TAKEN BY THE UNITED STATES AND T--ETC(U)
JUN 80 R J BRAUCHLER
UNCLASSIFIED AFIT-CI-80-547T NL



END
DATE FILMED
11-81
DTIC

A COMPARISON OF THE APPROACHES TAKEN BY THE UNITED STATES AND THE UNION OF SOVIET SOCIALIST REPUBLICS IN ESTABLISHING OCCUPATIONAL HEALTH STANDARDS

by

ROBERT JOHN BRAUCHLER, B.S., R.N.

THESIS

Presented to the Faculty of The University of Texas
Health Science Center at Houston
School of Public Health
in Partial Fulfillment
of the Requirements
for the Degree of

MASTER OF PUBLIC HEALTH

THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER AT HOUSTON

June 1980

Union of the Soviet Socialist Republics

UNCLASS

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

REPORT DOCUMENTATION PAGE		READ INSTRUCTIONS BEFORE COMPLETING FORM
1 REPORT NUMBER: 80-54T	2 GOVT ACCESSION NO: AD-A106 423	3 RECIPIENT'S CATALOG NUMBER
4 TITLE (and Subtitle): A Comparison of the Approaches Taken by the U.S. and the U.S.S.R. in Establishing Health Standards.		5 TYPE OF REPORT & PERIOD COVERED: THESIS/DISSERTATION
		6 PERFORMING ORG. REPORT NUMBER
7 AUTHOR(s): Robert John Brauchler		8 CONTRACT OR GRANT NUMBER(s)
9 PERFORMING ORGANIZATION NAME AND ADDRESS: AFIT STUDENT AT: University of Texas		10 PROGRAM ELEMENT PROJECT, TASK AREA & WORK UNIT NUMBERS
11 CONTROLLING OFFICE NAME AND ADDRESS: AFIT/NR WPAFB OH 45433		12 REPORT DATE: June 1980
		13 NUMBER OF PAGES: 59
14 MONITORING AGENCY NAME & ADDRESS (if different from Controlling Office)		15 SECURITY CLASS. (of this report): UNCLASS
		15a DECLASSIFICATION/DOWNGRADING SCHEDULE

16 DISTRIBUTION STATEMENT (of this Report)

APPROVED FOR PUBLIC RELEASE; DISTRIBUTION UNLIMITED

17 DISTRIBUTION STATEMENT (of the abstract entered in Block 20, if different from Report)

22 OCT 1981

18 SUPPLEMENTARY NOTES

APPROVED FOR PUBLIC RELEASE: IAW AFR 190-17

FREDRIC C. LYNCH, Major, USAF
Director of Public Affairs
Air Force Institute of Technology (ATC)
Wright-Patterson AFB, OH 45433

19 KEY WORDS (Continue on reverse side if necessary and identify by block number)

20 ABSTRACT (Continue on reverse side if necessary and identify by block number)

ATTACHED

DD FORM 1 JAN 73 1473 EDITION OF 1 NOV 65 IS OBSOLETE

UNCLASS 81103004

SECURITY CLASSIFICATION OF THIS PAGE (When Data Entered)

ABSTRACT

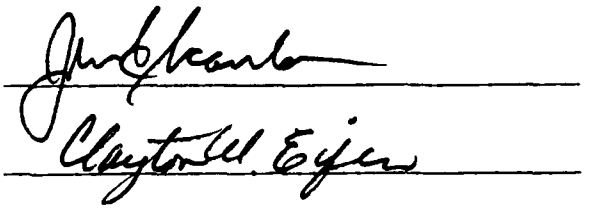
A review of the literature is given. Efforts of several international organizations to promote closer agreement of US and USSR public health value is covered. The report points out the difference in approaches taken by the two countries. Trends in recommended stadnards that have occured in the past 20 years is discussed.

A COMPARISON OF THE APPROACHES TAKEN BY THE UNITED STATES AND THE UNION OF SOVIET SOCIALIST REPUBLICS IN ESTABLISHING OCCUPATIONAL HEALTH STANDARDS

By

Robert John Brauchler

APPROVED:



_____

_____

_____

ACKNOWLEDGEMENTS

I would like to express my appreciation to the following for their support of my research for this thesis:

To Dr. Edward Fairchild, my thesis advisor, for his encouragement, expert advice, time, and valuable literature resources;

To Dr. John Scanlon, my academic advisor, for his advice and gentle but relentless attempts to motivate me to complete this thesis;

To the members of my advisory committee, Drs. Clayton Eifler and Benjamin Bradshaw, for their extremely helpful advice, comments and constructive criticisms that have greatly contributed to this thesis;

To the United States Air Force Institute of Technology for providing me the opportunity to participate in this academic program;

To my wife, Audrey, for her many long hours of typing, and her patience as she awaited the day when this thesis would be completed and I would be able to return to my normal family obligations.

Thesis presented to committee May 30, 1980

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER I
INTRODUCTION

The development and modernization of industry and agriculture often create occupational hazards, such as damage to health from the use of radioactive isotopes, injuries from machinery, and the entry of harmful substances into the body. In numerous industries, workers must handle potentially toxic chemicals. Furthermore, chemical reactions involved in certain manufacturing processes result in the liberation of toxic substances. As a result, acute poisoning, or more insidious damage to the health of the individual, his family, and perhaps the community, may occur with resultant adverse effects on productivity. However, the degree of risk of handling a given substance is not directly related to its known toxicity.

Removal of a hazard at its source, which gives complete safety to the worker, is one of the control methods commonly used. However, it is not always possible totally to enclose a process or to replace a potentially toxic substance by a harmless one. Consequently, where exposure to toxic substances is unavoidable, there has for many years been increasing reliance on the use of permissible levels. The main objective of the application of permissible levels should be "to maintain an optimum state of physical, mental, and social well-being in the working population" (WHO, 1977). A permissible level (PL) has been defined as "a concentration with a defined average time" (WHO, 1969).

Despite international agreement on the objective of the application and definition of PL's, the limits recommended for given chemicals often vary

from one country to another with the greatest variance noted between PL's established in the Union of Soviet Socialist Republics (USSR) and those established in the United States (US). The Soviet PL's almost invariably are lower than those of the US and differ by as much as a factor of 90 in some instances. This fact has been the source of extensive international efforts to promote better agreement of the recommended PL values between these two countries.

Several questions arise concerning the above mentioned facts: (1) why is it of international importance for the US and USSR PL values to be in close agreement?; (2) why are the values at such great variance?; (3) will these PL's be in closer agreement in the future? and; (4) which values are the most appropriate and/or correct? In order to find the answers to these questions, a review of the available literature was conducted and as a result of the information obtained, the subsequent sections of this paper are presented. The first chapter summarizes the efforts by several international organizations to promote closer agreement of US and USSR PL values. The second chapter points out differences in approaches taken by these two countries in deriving PL's and offers possible explanations for their adopting these approaches. The last chapter presents some changes that are occurring in the existing adopted approaches and methods used by both countries and reveals some trends in the recommended standards that have occurred during the past 20 years. Finally, the question as to which values are appropriate and/or correct will be dealt with in the conclusion.

There are several terms used throughout this paper such as threshold limit value (TLV), maximum permissible limit (MPL) and maximum acceptable concentration (MAC) that may need some clarification. Although these

different terms were adopted to emphasize certain differences among them, they all have the same purpose - namely to identify and locate a point on the dosage scale above which there is an increasing probability of injury, frank illness, and even death, but below which the risk is so limited that there is no serious threat to health, however long the exposure is continued. For simplicity, and in keeping with international practice, permissible level (PL) is used to include all the other terms with the exception that in certain comparisons the Soviet PL's are referred to as MAC's and the US PL's as TLV's.

CHAPTER II
INTERNATIONAL PERMISSIBLE LEVELS

In an effort to promote and maintain health, the World Health Organization (WHO) has recognized the important role that permissible levels have played in reducing occupational exposures to toxic substances. That is why this organization and other international organizations such as the International Labour Organization (ILO) have for many years attempted to improve the validity of these PL's and widen their use.

As a result of their efforts, PL's have been developed in an increasing number of countries so that today they are a basic factor in the protection of workers' health. However, recommendations and standards presented by various governments for the control of the same agent "appear to diverge much more than one would expect from the available scientific information for a particular agent" (Fairchild, 1979). Table 1 illustrates a few of these divergences.

These great divergences in recommended PL' s have been the source of extensive discussions both at the national and international level, as evidenced by several WHO Expert Committee Reports with participation of the ILO (WHO, 1969; WHO, 1977), exchange missions between the US and Soviet scientists (e.g., Magnuson, et al., 1964), United Nations Agency Conferences of International Scientific consultants (ILO-WHO Joint Committee Report, 1970) and International Symposia of Occupational Health Organizations (e.g., Prague 1959 Symposium).

More recently, programs have been developed by WHO in an effort to promote an international exchange of information among specialists for the

TABLE 1
PL VALUES* FOR VARIOUS SUBSTANCES IN VARIOUS COUNTRIES

COUNTRIES / SUBSTANCES	AUSTRL	BULGAR	CZECHO	FINLD	GDR	FRG	JAPAN	NETHLD	POL	SUISS	USSR	USA	YUGO
Acetaldehyde	180	-	-	180	100	360	-	180	100	180	5	360	360
Benzene	80	-	50	32	50	-	80	30	30	32	5	30	50
1,2-Dichloro-ethane	200	-	50	200	50	80	200	200	10	80	10	200	-
Epichloro-hydrin	19	-	-	19	5	18	-	19	1	19	1	19	18
Hexane	1800	-	-	1800	-	360	360	360	400	360	-	1800	410
Malathion	-	0.6	-	10	-	15	-	10	15	10	0.5	15	0.5
Propylene chloride	350	10	-	350	50	350	-	350	50	350	10	350	350
Styrene	420	5	200	420	200	420	210	420	100	420	5	420	420
Toluene	375	50	200	750	200	750	375	375	100	380	50	375	200
Xylene	435	50	200	435	200	870	670	435	100	435	50	435	50

*All permissible level values given as Mg/M^3

Source: Fairchild, E. J. (1979) International Perspectives in Occupational Health Standards and PL's. From speech material presented at the American Industrial Hygiene Conference, May 31, 1979. Chicago, IL. (in press)

purpose of developing closer agreement on PL's. One of these programs is the "WHO PL Programme" which is officially titled "International Recommended Health-based Permissible Levels For Occupational Exposure to Chemical Agents". According to Fairchild (1979) this program attempts to establish internationally recommended permissible levels for harmful substances and promote standardization of methods of evaluation of harmful effects.

The first step of the program is to establish priorities for various harmful substances that are in need of having international PL agreement. Various criteria are used to set these priorities such as:

> (1) the numbers of workers who have potential for exposure, and the frequency of exposure; (2) the degree of toxicity of the agent; (3) the magnitude of the morbidity from exposures in different parts of the world, and; (4) the degree of difference between PL values of the US and USSR for the substance (Fairchild, 1979).

The fourth criterion is of particular importance in that it is based on the general acceptance that the US and USSR are the leading countries in development of PL's and that for many important substances these PL's are at the greatest variance. It is felt by members of the "WHO PL Programme" that any substances with a PL variance factor greater than 2; that is, if the ratio between the US PL and the USSR PL for the same substance is greater than 2, the criterion of variance is met and that substance is given high priority for international discussion and promotion of closer agreement. Figure 1 shows an example of this type of calculation. In addition, Table 2 illustrates how the above mentioned criteria have been applied in setting priorities for the heavy metals. Notice that only the first four heavy metals listed meet all the criteria and therefore, are given highest priority for promotion of international discussion and agreement on recommended PL values. In addition to the heavy metals, the "WHO PL Programme" plans to develop in-

ternational health-based recommendations for priority solvents, pesticides, dusts, and respiratory irritants (Fairchild, 1979).

Figure 1
Calculation of Permissible Level (PL) Factor of Variance (fv)

$$\frac{\text{PL VALUE IN USA}^{1}}{\text{PL VALUE IN USSR}} > 2$$

Example: Trichlorethylene

$$\frac{535\ \text{Mg/M}^3}{10\ \text{Mg/M}^3} = 53.5 = \text{fv}$$

or

$$\frac{\text{PL VALUE IN USSR}}{\text{PL VALUE IN USA}} > 2$$

Example: Selenium

$$\frac{2\ \text{Mg/M}^3}{0.2\ \text{Mg/M}^3} = 10 = \text{fv}$$

1. USA Values represent both the official Occupational Safety and Health Administration values and the American Conference of Governmental Industrial Hygienist TLV's.

Source: Fairchild, E. J. (1979) International Perspectives in Occupational Health Standards and PL's. Speech material presented at The American Industrial Hygiene Conference, May 31, 1979. Chicago, IL. (in press).

TABLE 2
APPLICATION OF "WHO PL PROGRAMME" CRITERIA FOR PRIORITY HEAVY METALS

SUBSTANCE	CRITERION[1]				
	1	2	3	4	fv[2]
Cadmium	✓	✓	✓	✓	3.3
Lead	✓	✓	✓	✓	15.0
Manganese	✓	✓	✓	✓	17.0
Mercury	✓	✓	✓	✓	20.0
Nickel	✓	✓	-	✓	2.0
Vanadium	✓	✓	✓	-	0.5

1. Positive sign (✓) indicates that criterion is met, and (-) not met.
2. fv = factor of variance = Ratio of US PL Value/USSR PL Value.

Criteria: 1 - the number of workers who have potential for exposure, and the frequency of exposure.
2 - the degree of toxicity of the agent.
3 - the magnitude of the morbidity from exposures in different parts of the world.
4 - the degree of differences between PL values of the US and USSR for the substance (factor of variance).

Source: Fairchild, E. J. (1979) International Perspectives in Occupational Health Standards and PL's. Speech material presented at The American Industrial Hygiene Conference, May 31, 1979. Chicago, IL. (in press).

The "WHO PL Programme" does not represent the first attempt to compose a list of internationally accepted PL's. Truhaut (1963, in ILO, 1970) was one of the first to develop an approach to composing such a list. He suggested that the list of limits should not be regarded as "lines of demarcation between harmless and dangerous concentrations, but as guides, indicating zones of maximum tolerable concentrations, at least as a first approach". In contrast to the approach taken by the "WHO PL Programme", Truhaut regarded substances with a factor of variance of no more than 3 as close enough in agreement to be incorporated into a list of internationally accepted PL's. That is, the substance would be added to the list if the ratio of US PL/USSR PL was no greater than 3.

In 1969 the same approach was taken by a Joint International Labour Organization/WHO Committee on Occupational Health (WHO, 1969). This committee compared the most recent PL's established by the USSR with those of the American Conference of Governmental Industrial Hygienists (ACGIH) and using the criterion that the PL's not differ by a factor of greater than 2, they were able to show close agreement for 24 substances a list of safe concentration zones that could be recommended for international use. Unfortunately, these 24 substances only represent approximately 5% of the 500 substances considered by this committee. However, at present there is in preparation for agreement, another 53 chemical agents for which there may possibly be developed an internationally accepted list of PL values (Fairchild, 1979).

It is apparent, at least in the opinion of WHO, that the key to international occupational standards is the closer agreement between US and Soviet maximum permissible limits (MPL's). It is believed that if the stand-

ards of these two countries can be more closely approximated, the remaining countries of the world will also be in closer agreement due to the tremendous influence that both the US and USSR have on them.

When one compares the different industrial countries of the world with respect to the process of developing occupational health standards, it is immediately obvious that each industrial nation follows the lead of either the US or the USSR. These two countries assume the strong leadership positions in the environmental domain as a result of a combination of historical and political factors, in addition to economic considerations.

The vast majority of research on which occupational standards may be derived is conducted in the US and the USSR primarily because of their vast economic resources. Dinman (1976a), quoting from the Czechoslovak Commission for Maximum Allowable Concentrations, illustrates this point:

> we are fully aware that it is beyond the power of a small country to work out alone proposals for a large number of industrial chemicals. They are mostly dependent on information from the literature which they compare with their own experience.

Though it would be expected that Socialist countries would completely adopt a list of standards established by the Soviet Union and the Western industrial countries would look to the US for guidance, this is not always the case. Limitations simply of economic resources preclude the ability of many Socialist nations to provide environmental controls inherent in the meeting of Soviet standards (Calabrese, 1978). As Dinman (1976a) bluntly stated, "While espousing the political philosophy of the Soviet system, it appears that economic actuality ultimately prevails over dogma". Tables 3 and 4 summarize the extent and scope of industrial standards in various Eastern Bloc

TABLE 3
COMMENTS ON OCCUPATIONAL HEALTH STANDARDS IN EASTERN BLOC COUNTRIES

Bulgaria	Czechoslovakia	Hungary	Poland	Romania
Lists MAC's[1] for 120 substances; for those unlisted substances, Soviet standards are considered legally binding. Governmental standards are considered legally binding.	In 1966, listed 68 MAC values--in all but 3, short-term single excursion was allowed. In 1976, MAC values listed as TWA's[2] with some maximum limits. For unlisted substances, Soviet MAC values are recommended but as TWA's, not maximum limits. No indication if these values are legally binding.	In 1965, listed 104 MAC values for gases and vapors and 6 MAC's for dusts. Used TWA instead of maximum limits. Standards are legally binding.	Listed 210 gases, vapors and dusts and 14 compounds. Some excursion above MAC values allowed with permission from specific Health Inspectors. MAC's for the 14 compounds are legally binding, but there is no identification if the other MAC's are also legally binding.	In 1966, listed 472 MAC values for gases and vapors plus 10 MAC values for dusts. MAC values are listed as either maximum limits or TWA's. Standards are legally binding.

1. MAC - Maximum Allowable Concentrations
2. TWA - Time-Weighted Average
3. PL - Permissable Level (table 4)
4. ACGIH - American Conference of Governmental Industrial Hygienists

Revised and augmented from Calabrese, 1978.
Sources for revision: ILO, 1977; and Dinman, 1976a.

TABLE 4
COMMENTS ON OCCUPATIONAL HEALTH STANDARDS IN WESTERN COUNTRIES

France	Italy	Sweden	United Kingdom	West Germany
Use of MAC's is not encouraged. No official lists of PL's[3] published. Private voluntary organization (Assoication Interprofessionalle des Centres Medicaux et Sociaux of the Paris region) publishes list of PL's largely adopted from the US ACGIH[4] (as guides to goverment).	There was very low activity with regard to setting industrial health standards until 1975; Dinman (1976a) reported only 7 industrial standards. In 1975, the list included over 165 PL values with most being adopted from the US ACGIH list. There is no evidence that these PL's are legally binding.	The lists of PL values are issued by the National Board of Industrial Safety and Health. Most PL's listed are based on ACGIH values; are either TWA or Ceiling Limit Values. The PL values are not regarded as mandatory standards.	The list of PL values is almost entirely adopted from the US ACGIH list. Recent changes to many of these PL's have been due to recommendations from a committee of scientists, workers, employers and government officials thus obtaining practical PL's from a consensus of opinions. In general, PL's are not legally binding. However, some have been embodied in Codes of Practice.	A non-governmental group (Commission for Evaluation of Toxic Materials in the Workplace) has published 144 MAC's (as of 1972). The original values were based almost entirely on ACGIH values. However, now the even more extensive list is completely independent of the US lists. MAC's are listed as either TWA's or Ceiling Limits. They are not enforced by law but are used as guides to government agencies.

Same source and footnotes as Table 3.

and Western countries (not including the US and USSR). It is interesting to note how many countries either in the past or at present base their standards on those of the ACGIH. The Bulgarian approach is nearly identical to that of the Soviet Union, whereas other Eastern countries show a certain degree of individuality in their approaches to the setting of occupational health standards. For example, Hungary has adopted the use of time-weighted averages (TWA's), in marked contrast to the MAC's of the Soviet Union which are considered to be limits that are not to be exceeded. The TWA approach is one taken by the US in which excursions above the limits are permitted as long as the average of the exposure during the workday does not exceed the recommended limit. These tables also reveal the patterns of the influence of underlying legal systems upon the standard setting process. Depending on legal philosophies, standards listed by various countries may or may not represent standards promulgated by governmental bodies and as such may or may not be legally binding. In the Western countries, the pattern largely follows that of the US before the Occupational Safety and Health Act of 1970, i.e., recommendations by non-governmental bodies. As recommendations, they might or might not be embodied in labor codes and be considered as law. By contrast, while the Socialist nations utilize commissions with at least some form of official status, the recommendations are embodied in an official code which is of a legally binding nature (Dinman, 1976a).

Similarly, the US and USSR play an important role in the influence of the development of occupational health standards in industrially developing countries. These developing countries, like the industrially established countries, will likely be restricted by economics and technology in attempting to derive their own standards. Accordingly, they too will be forced to adopt

the standards of either the US or USSR. The decision as to whose standards they will adopt will most likely be influenced by the same factors that affect the decisions of the industrially established nations (i.e., political, cultural, economic, etc.).

However, these developing countries may have additional factors (i.e., poor living conditions, epidemic and endemic diseases, severe climatic conditions, poor geographical situations and conflicting cultural attitudes toward health) that must be considered and greatly emphasize the need to choose the proper health standards.

In addition, through the years, the price of rapid industrialization has been dear. Great numbers of occupationally-related diseases and deaths have occurred and are still occurring. It seems that all industrial nations have paid this price at one time or another during the course of industrialization and have and still are experiencing increased risk to human health as a result of exposure to an ever increasing number of toxic substances. If the developing countries were to suffer the same fate in their populations, coupled with an already existing poor national health status, the results would be devastating.

The World Health Organization, with the help of other international organizations is attempting to prevent occupational health catastrophes from occurring in these developing nations. WHO has organized committees made up of experts in a variety of scientific fields and from many different countries in an effort to gather as much information as possible regarding methods used in establishing permissible levels in occupational exposure to harmful agents. One such committee met in 1977 (WHO, 1977) and through the exchange of information on various methods used in several countries was able to reach an

agreement on the best known accepted methods in experimental and epidemiological studies that can be used as a basis for establishing PL's. The results of the consensus of opinions of this committee was published as guidelines (WHO, 1977) that may be used by industrial countries and developing countries in providing guidance for the selection of the proper methods to be used in establishing meaningful standards that can be applied to each country's unique situation.

The WHO guidelines for establishing PL's is an excellent idea and may, in fact, be of great assistance to industrially developing countries. It may also bring about a closer agreement between the approaches used by the US and the USSR in establishing PL's. However, the major differences between the approaches taken and the values obtained between these two countries must be examined more closely before any real hope for internationally accepted standards can be considered.

CHAPTER III
DIFFERENCES IN THE APPROACHES TAKEN BY THE US AND USSR

There are several important areas in which the US and USSR differ in their approaches to establishing PL's which explain why these values are at such great divergence. This chapter points out some of these differences with emphasis on the Soviet approaches and methods. Several of the opposing approaches are the result of the underlying philosophical concepts of the Soviets.

Philosophical Differences

To understand the basic underlying differences in approaches taken by the US and USSR in establishing PL's for toxic substances, it is necessary to first understand the inseparable relationship of political considerations with scientific thought as is the case in Socialist countries (Dinman, 1976a).

According to Calabrese (1978), commenting on Dinman's (1976a) article on the development of workplace standards in foreign countries, the Soviet approach to the development of criteria for the derivation of permissible limits follows from their philosophical views on the nature of man, which were derived in large part from the writings and teachings of Marx and Lenin. "Perhaps the critical factor in this process is the synthesis of the writing of Lenin with the work of Pavlov on higher nervous system function" (Calabrese, 1978).

The unity of thought with respect to Marx, Lenin and Pavlov stems from the fact that they tried to explain man totally in mechanistic terms. Thus the adoption of Darwin's theory of evolution by Marx offered Lenin the

"geobiologic-historic" foundations for considering man in terms of biologic adaptation (Calabrese, 1978). Thus the scientific foundations for Lenin's rejection of the dualism of body and mind as developed by Descartes were founded in the acceptance of a mechanistic concept of evolutionary theory. At the experimental level, Pavlov also rejected Cartesian dualism of body and mind, and according to Dinman, this suited Lenin's needs very well (Calabrese, 1978).

According to Pavlov, the brain is in a constant state of balance, regulating its functioning to acquire a balance between external and internal stimuli by effecting inhibitory and stimulatory responses. The cerebral cortex is considered the principal regulator of such activity; it is also in dynamic equilibrium with subcortical, stem, and visceral regulatory centers that control the body's homeostatic processes. Thus, Pavlov considered nearly all of man's activity as fundamentally under the control of the cortex (Dinman, 1976a).

Various attempts have been made to translate Lenin's thought into physiologic perspectives analogous to Pavlov's terminology. For example, Dinman (1976a), quoting Kupalov et al., indicated that:

> according to Lenin ... the dialectical way to consciousness of objective reality procedes from active contemplation (similar to Pavlov's First Signal System) to abstract thought (Pavlov's Second Signal of Activity) and thence to practical application, i.e, the experimental testing of abstract thought. Consequently, the relationship between dialectic-materialistic theory of consciousness of Marxism-Leninism and Pavlov is intimate and reinforcing.

Dinman (1976a) points out that it is the unique synthesis of Lenin's and Pavlov's thought that ultimately influenced the importance of reflex behavior in the standard derivation process in the USSR. He further stated that experimental procedures that question the validity of the Pavlovian perspective

can be logically thought to be a threat to the foundations of Soviet biologic science. Thus permissible limits not primarily derived from Pavlovian principles are not seriously considered.

The interpretation and application of these philosophical concepts by the Soviet scientists may be the basis for the general disagreement between the US and USSR as to whether changes in neurological activity constitutes an adverse health effect. The reason why such responses are considered as "toxic or adverse" effects is that they are related to, and affect:

> instability of nervous regulation, arising against the background of a changed functional state of the cortex and subcortical region. These are believed in turn to lead to altered reactivity of the vascular and endocrine systems and instability of neuro-circulatory processes. The manifestations of such changes in the affected individual are the general, non-specific symptoms of toxicity arising from such autonomic dysequilibrium (Dinman, 1976b).

This represents the principal philosophical and scientific argument used by the Soviet toxicologists to support the need for using neurophysiologic indicators of pollutant toxicity and provides the basis for their belief of what constitutes an adverse health effect.

The adverse effect controversy

The concept of a permissible level of exposure to a substance known to be potentially toxic emphasized the quantitative characteristic of the dose-response relationship; that is, a graded decrease is found in the magnitude of the biological response as the dose of the toxic material is lowered (Hatch 1976a). On the basis of the demonstrated reality of such a quantitative dose-response relation, Smyth (1976) stated "... substances are neither harmful nor harmless. It is the quantity that causes harm". From this it can be argued that there is a tolerable dosage rate above zero for all toxic materials. This thinking has led to the functional concept of threshold limit values, as explained by Stokinger (1972), as that concentration at which an individual

could be exposed for a considerable length of time without experiencing an adverse health effect. This concept of threshold representing a nonlinear relationship between dose and subsequent responses is the fundamental basis for toxicological studies in both the US and USSR. However, although there is general agreement on the general principles of dose-response relationships, there is considerable controversy over the types of responses that are considered significant as indicators of an adverse health effect.

In the US, dose-response studies are started at a level of dosage at which demonstrable ill effects are noted in the test subject. Testing continues in a downward direction with lower and lower doses, and, as the responses to these doses becomes less and less detectable, increasingly sensitive tests for pre-clinical, physiological, biochemical, and functional disturbances are used to demonstrate resulting toxic effects (Hatch 1972a). These sensitive new tests are constantly being subjected to critical evaluation of their usefulness in terms of their significance as predictors of ill health (Stokinger, 1969).

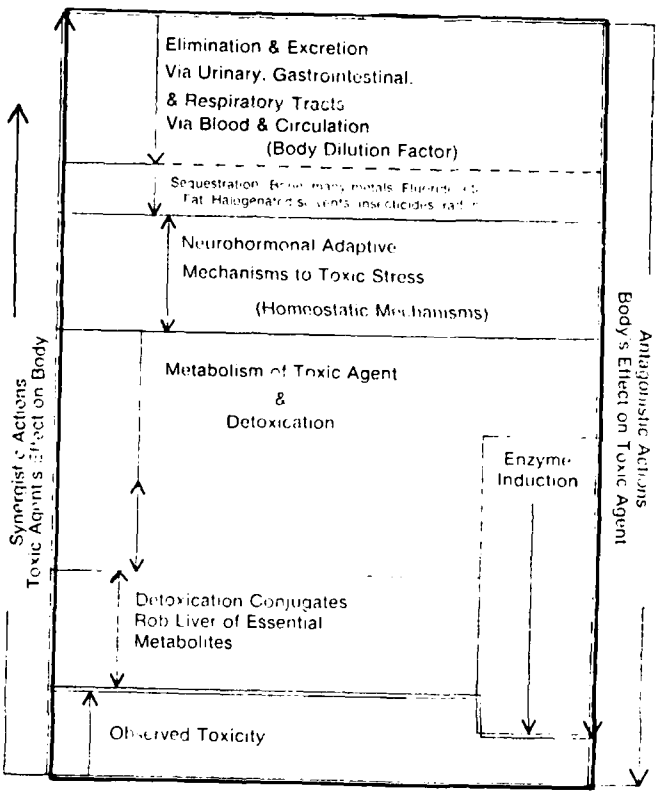
In the USSR, in addition to such studies in the physiological and biochemical areas just below the pre-clinical, emphasis is placed on starting from the opposite (lower) end of the dose-response relation and by working up from zero dose and an initial standard of normality in the test organism, highly sensitive measurements of behavioral or other response are used to establish the permissible limit, which is considered to be just below the lowest level of exposure needed to induce a statistically significant deviation from the normal state (Sanockij, 1975).

These are two basically different concepts. In the first, no serious threat to health is considered to exist as long as the level of exposure

does not induce in the organism "a demonstrable disturbance of a kind and degree that is accepted as an indication of potential sickness" (Hatch, 1972b); in the second, a potential for ill health is said to exist as soon as the organism undergoes the first detectable change of any kind from its normal state (Hatch, 1972a). In the US concept, the "accepted indication of potential sickness" as stated by Hatch (1972b) is one that overloads the normal protective mechanisms of the body.

The general opinion in the US is that experimental animals and humans respond to pollutant exposure with a natural process of adaptation. Adaptive responses are seen as homeostatic processes by which an organism protects itself. These defense mechanisms can be safely drawn upon, within certain limits of permissible load, to offset the levels of stress imposed by minimum exposure to hazardous agents at the workplace, just as they are regularly called upon to counter the wear and tear of ordinary living (Hatch, 1972a and Stokinger, 1972). In addition, Stokinger (1972) states that the existance of adaptive responses is the most convincing physiologic argument supporting the biologic reality of thresholds. He further explains that toxicity may be conceptualized as the result of two competing reactions - one is the action of the toxicant on the body, and the competing response is the adaptive (or homeostatic) action. Thus toxicity may result only when the adaptive responses have not been sufficient to overcome the action of the toxicants (Figure 2). This concept has been verified in numerous organisms, including humans, and with numerous substances. Stokinger (1972) gave as examples; the well known existance of thresholds for numerous sensory irritants of the eyes, nose, and throat and; the results of studies indicating the body's capacity to adapt to toxic elements such as certain metals.

FIGURE 2
ANALYSIS OF THE EFFECTS OF A TOXIC SUBSTANCE



Source: Stokinger, Concepts of thresholds in standard setting. Arch Environ Health 25:155. Copyright 1972, American Medical Association.

The contrasting view of the Soviets is that the protective mechanisms or defense mechanisms that maintain homeostais should be saved for use only under emergency conditions to take care of unexpected insults and that their effectiveness should not be weakened by the continuing demands of avoidable stress, knowingly permitted at the workplace. In the extreme, this view holds that only a zero concentration of the toxic agent will remove all health risk; short of this, it permits no significant departure from the normal behavior of the organism in consequence of exposure to the offending substance (Hatch, 1972a). The Soviet concept of an unacceptable response was apparent in 1954 when they established the following principle (Rjazanov, 1962) for ambient air quality standards: "Any stimulus, whether agreeable or not, becomes disagreeable, intolerable and sometimes pathogenic, if the stimulus has a forced character (cannot be avoided)". This means that any forced stimulus with any effect is unacceptable. In addition, Medved et al.(1966, quoted by Zielhuis, 1974) gave as criteria for acceptability of a permissible limit not only: "absence of any pathological change or disease" but also" "absence of any changes which can become pathological under prolonged exposure". Subsequently, the official definition of Maximum Allowable Concentration as adopted in the USSR is stated by Sanockij (1975) as:

> Maximum allowable concentrations of harmful substances in the air of the working area are those concentrations that, in the case of daily exposure at work for 8 hours throughout the entire working life, will not cause any diseases or deviations from a normal state of health detectable by current methods of investigations, either during the work itself or in the long term.

Thus, it is of little wonder that the majority of the Soviet established PL's are so low, especially when you consider that the "deviations from a normal state of health" are in most cases measurements of changes in central nervous activities.

Soviet emphasis on studies of the central nervous system

Another philosophically-based approach of the Soviets in establishing PL's is their heavy reliance upon central nervous system activities. The approach of medical research in Western Europe and the US has traditionally been oriented towards cell and organ alterations and biochemical changes as early indicators of diseases. In the USSR attention has been directed more towards the integrated functional response of the organism, taking into account specific and non-specific changes in the function of the higher nervous system and regarding them as a signal of biological interaction between organism and noxious factor that may in fact lead to disease. The underlying reason for this Soviet approach, as mentioned previously, is based on the philosophical and scientific principles of Pavlov and Lenin, and it is the interpretation of these principles that has led to the Soviet reasoning that neurologic responses should be considered toxic or adverse effects.

Although Western scientists have generally disagreed with the Soviets for their "excessive" use of neuro-physiological responses as indicators of disease, the Soviet methods of functional studies of the nervous system evidently are considered to be of value by many experts in the field of industrial health. This is evidenced by the fact that these methods were included in the report of the WHO Expert Committee for "Methods Used In Establishing Permissible Levels In Occupational Exposure To Harmful Agents" (WHO, 1977). This report represents a consensus of opinions on the best methods to be used for establishing PL's.

According to Pavlenko (1975), studies of the response of the higher nervous activity of the organism to chronic exposure threshold quantities of toxic substances can be carried out only by using methods based on analytical

studies of the organism as a whole under conditions approaching those found in nature as closely as possible, including:

> (a) repeated studies of the initial state (background); (b) the study of the dynamics of functional change, due account being taken of the concentrations or doses of the substance in question; (c) studies of duration of the effect, and the reactivity of the organism; (d) a careful comparison of the indices under investigation in the test-objects and controls, etc. (Pavlenko, 1975).

Pavlenko explains that only under these conditions will it be possible to detect very small initial functional changes in the organism.

The Soviets use a wide variety of neurophysiologic testing methods which include; observational techniques; unconditioned reflex behavior and; conditioned relfex behavior. The majority of these tests are conducted on a variety of animal species including mice, rats, rabbits, cats, and in some studies, man. These various behavioral testing techniques are incorporated into the established Soviet methods for studying specific and non-specific changes in higher nervous activity as a result of toxic substance exposures. The changes in higher nervous activity, either as a result of a single exposure or by chronic exposure to threshold amounts of toxic substances, may be studied in three different ways, depending on the purposes and objectives in view (Pavlenko, 1975 and WHO, 1977):

> (1) initial tentative evaluation of the effect of the substance on the whole organism; (2) evaluation of the changes in the central nervous system on prolonged exposure to small amounts of the substance in order to establish the dose/response relationship; (3) investigation of functional changes in order to study the mechanism of action of the substance.

An initial appraisal of the effects on the central nervous system is necessary when studying an unknown substance. After administration of a single dose and without preparation of the animal, it may be possible to ascertain changes in orienting and defensive reflexes showing cortex and subcortex

involvement. In these experiments, use is made of stereotyped sets of stimuli such as auditory, tactile, and pain stimuli.

For substances with central neurotropic activity, the behavior of animals under exposure is studied with a set of more sensitive methods of focusing mainly on the evaluation of motor-activity, thus making it possible to detect any specific effect that the substance may have on higher nervous function and to determine whether behavioral effects are likely to develop on industrial exposure. The evaluation of changes in the central nervous system during long-term exposures to small concentrations of toxic substances requires precise and sensitive methods based on conditioned reflexes in a variety of laboratory animals.

Such exposures may result in the elimination of internal inhibition processes; there may even be loss of the conditioned reflex or an alteration of the stimulatory process with reduction of the strength of the response and disturbance of its pattern. The severity of the change and the time taken for it to develop depend on the concentration or the dose to which the animal has been exposed. In chronic inhalation experiments, phases of depression and activation of various functions may occur, showing the interactions between toxic effect and the adaptive mechanisms, which may lead to an apparent normalization of higher nervous system functions.

A simpler but still sensitive method involving the determination of the latent period of the response to an electrical stimulus has also been used to evaluate toxic effects. Stress tests are very useful in carrying out investigations on subtle functional changes owing to their high sensitivity to the latent effects produced by subthreshold doses of toxic substances (WHO, 1977; Pavlenko, 1975).

While the above mentioned methods used by the Soviets are considered by many to be theoretically excellent, some question the validity of the experimentally applied techniques and thus the results obtained. Dinman (1976b) pointed out several of the discrepancies noted in the Soviet experimental designs and techniques. Some of his comments follow:

> (1) Choice between unconditioned versus conditioned test - while unconditioned testing procedures are generally less sensitive to host change, they are relatively easier to perform and lend themselves readily to test-retest analysis. Unconditioned testing, however, does not generally indicate the involved physiological mechanism; (2) Choice of which conditioned reflex to utilize - generally it appears that defensive-action based reflexes are less sensitive to environmental change than are food based reflexes; (3) Choice of species - undoubtedly this question presents the same species variation problem seen with other toxicological studies; (4) Problem of standardization of independent variables - this is probably one of the most serious obstacles that neurophysiological test methods need to overcome. This problem becomes progressively more severe as the testing procedures become more complex. Higher nervous testing assumes some degree of neurostability, yet by definition, such test activity constitutes, in a dynamic state, an inherent incompatibility. This dynamic state is also markedly susceptible to intercurrent illness or pathology, aging, season, etc. Furthermore, experimentor variation can readily affect results obtained. Assessment of test phenomenon depends upon attention and concentration of the trainer, as well as relationships built up between him and the subject. In addition, repeated daily testing for weeks or months may lead to attention decrements on the trainer's part. This immediately raises a question as to comparability between various laboratory findings, a most serious problem in toxicity testing and (5) Statistical validity - this represents a problem area to which less attention than expected has been given in Soviet literature. In part, the fact that so many investigators using behavioral testing utilize relatively few animals reflects the time and cost involved in such experiments rather than reluctance to deal with statistically adequate numbers of experimental animals (Dinman, 1976b).

Similarly, Magnuson et al. (1964) after visiting the Soviet Union as part of an Exchange Agreement, also noted some of the same discrepancies to which Dinman eluded. Most notable was the lack of statistical validity due to the extremely small numbers of test animals used in their studies. In commenting on this obvious deficiency, Magnuson et al. (1964) stated, "because of the emphasis on

the minimal response to toxic change, we were left with the uncomfortable feeling that these responses were sometimes based on the results in one cat, or at best, a few cats".

Dinman (1972) questions the entire Soviet concept of establishing permissible limits based on the occurrence of changes in sensory input. He contended that to keep concentrations of environmental agents below one's level of perception may create:

> a creature (that) would have a Faustian life span but (one that) could receive no new knowledge, an existance barely removed from that of the amoeba in its ability to experience that world around it. The danger that a world oblated of sensory inputs imposes has been clearly demonstrated by sensory deprivation experiments. It seems that man is destined to fail and challenge, to perceive and appreciate his world, but at the cost of mortality. Otherwise, what an immortality, what a life! (Dinman, 1972).

Controlled Experiments versus Epidemiologic Studies

In the USSR an extremely heavy reliance is placed on the information gathered from animal and human experimentation with epidemiologic investigations assuming a much less significant role in establishing permissible limits. Conversely, in the US, epidemiologic studies when available play a major role in the permissible limit derivation process, and major emphasis is placed on animal and human experimentation only when epidemiology does not suffice.

Controlled experiments

Rjazanov (1965) and Izmerov (1973) outlined the experimental protocol used in the course of animal experimentation (Table 5) and from this protocol, Sanockij (1975) developed a multistage investigative procedure employed in the USSR that is required by law to be conducted on all new chemical substances prior to their production and use. It is interesting to note that the quantitative results of each stage of animal experimentation are used to es-

tablish complicated ratios of acute and chronic effects which are eventually used to calculate the established permissible limit for the chemical substance.

TABLE 5
TOXICOLOGIC PROCEDURES EMPLOYED TO SUPPORT STANDARD SETTING IN THE SOVIET UNION

Step 1. Identification of the chemical and physical characteristics of the toxicant substances (e.g., description of vapor pressure, solubility, flammability, etc).

Step 2. Acute Toxicity
- A. Animal studies
  1. Mice studies
     - -Static exposures
     - -Two hours/day for 3 weeks
  2. Rat studies
     - -Static exposures
     - -Fours/day for 3 weeks
- B. Purpose
  - -Define lethal concentrations
  - -Determine the clinical sequence
  - -Characterize changes in the conditioned and direct reflexes

Step 3. Subacute exposure-four hours/day for 6 days/week for one to two months

Step 4. Chronic Exposure
- -Use of multiple species
- -Exposure for 4 hours/day, 6 days/week for 5-6 months
- -Chronic studies include (1) microscopic changes in various organ systems including brain, heart, liver, spleen, kidney, or lung; (2) biochemical indicator tests

Step 5. Accumulation Studies

Source: Calabrese, E. J. (1978) Methodological Approaches to Deriving Environmental and Occupational Health Standards, p. 336, John Wiley & Sons, Inc.

An example of these calculations can be seen in a subsequent section on "Safety Factors".

In addition to the tremendous use of monitoring techniques for changes in nervous activity as previously mentioned, consideration is also given to other sensitive indicators of pollutant exposure. For example, urinary excretion levels of coproporphyrin are used to monitor exposures to a variety of substances such as carbon dioxide, dinile, styrene, and dimethyl formamide, which decrease coproporphyrin levels, whereas lead and toluene diisocyanate increases them (Calabrese, 1978). Other studies of biologic monitoring include examining the potential effects of changes in the degree of dispersion of the serum proteins such as the ratios of globulins and albumins. Dinman (1976a) also pointed out that the Soviets make use of many of the same toxicological studies as used in the US although their preoccupation with the role of the central nervous system greatly influences the emphasis they place on certain types of tests and also the effects that they report. For example, pathological investigations similar to those used in the US for evaluation of structural change of various organs and systems is directed largely towards pathology of the central nervous system. Likewise, endocrine studies are intensely studied in the USSR because of the clear linkage of humoral factor elaboration and control with neural function. Dinman (1976a) was very impressed with the Soviet immunologic studies especially those that have shown the affect of chemical toxicants on the course of several diseases (e.g., the effect of low concentrations of mercury on the course of Influenza A in animals). He stated that "such studies reflect a particular segment of concern, i.e., combined effects of toxicity and infection. These represent an area of practical importance"(Dinman, 1976a).

Epidemiologic studies

In the US, one of the most valuable sources of information used in

developing permissible limits for various chemical substances is the epidemiologic study in which the effects of the specific pollutant on an exposed population are studied. Its value lies in the fact that data are derived from human subjects as compared with animal models. However, in contrast to controlled animal and human experiments, epidemiologic study incorporates numerous potentially uncontrolled variables that tend to weaken the confidence of any disease-pollutant association. Despite their limitations, epidemiologic studies have been greatly improved and have provided much of our knowledge of toxicity to humans of arsenic, asbestos, lead, mercury, and numerous other pollutants. For toxic substances that have been in the environment for many years, primarily as a result of industrial processes and for re-evaluating previously established PL's, the epidemiologic studies are probably the most important source of information. However, for newly developed chemicals that have not been widely distributed in the environment, data from animal model studies may provide the best indication of potential toxicity to humans. Thus the Soviets, in an attempt to prevent hazardous exposures from occurring, emphasize establishing more precise PL's based on laboratory studies of animals.

The Soviets contend that information derived from morbidity studies is not considered to be of significant help in derivation of PL's, since they relate information of harmful levels and not how low a level must be to be considered "safe". Furthermore, Rjazanov (1965) noted that there often is a very wide range of concentrations between the toxic and "safe" levels. This transitional zone, although not invoking pathological responses, does cause the occurrence of adaptational and protective mechanisms and that such changes cannot be permitted. He concluded that the mere existance of such protective changes is clear evidence of the presence of an unacceptable environment and

that PL's must be set at levels that are sufficiently low so as not to evoke these changes. Thus, even though morbidity studies can help substantiate that pollutant levels may be too high, they cannot tell what the PL's should be (Rjazanov, 1965).

Prediction of PL's

In the past, toxicologists in the US would attempt to estimate an approximate TLV by extrapolation by chemical analogy. This procedure applies the principle that the quality of response of a chemical may be assumed to be analogous to that produced by similar substances; that is, chemicals that are structurally similar should produce a similar biological response. By using a chemical with an established TLV that is comparable in structure or action, an approximation of a TLV can be established for a new chemical substance that has not as yet been studied by more precise methods. However, this method was found to have several limitations(i.e., one compound in a chemical family of compounds will respond in a totally atypical manner when compared with others of that family) and it was determined that there was considerable risk in establishing a PL based on an assumption only. Thus, US PL's no longer rely so much on chemical analogy but are instead based on stringent toxicological and epidemiological procedures for study.

In contrast to the methodologic procedures in the US, Soviet scientists devote considerable effort to trying to predict toxicity for organic compounds on the basis of physical and chemical properties (Ljublina and Filov, 1975). These researchers have presented their attempts to derive regression equations of physical properties (molecular weight, specific gravity, vapor pressure, boiling and melting points, refractional index, and surface tension) for a variety of related substances whose maximum permissible concentrations

are known. Based on such calculations, it is hoped that the potential toxicity of a substance may be predicted. These calculations are usually conducted on new chemical substances that have not as yet been introduced into the industrial environment and serve as an approximation of toxicity and estimate of a PL. From these approximations, priority lists of substances intended to be given further toxicity tests may be developed. Usually such calculations are conducted concurrently with toxicologic investigations with the results being reported to both scientific and design organizations (Sanockij, 1975). Calabrese (1978) and Dinman (1976c) both agreed that the use of these calculations to predict PL's, although not likely to be strongly adopted in the standard derivation process in the US, has potential usefulness and should be explored more fully.

Safety Factors

Safety factors are an integral part of the derivation process of PL's in both the US and USSR. Although the Soviets refer to them as "reserve co-efficients", they are intended to be used for the same purpose in both countries; that is, to provide for a wider margin of safety for individuals at risk of exposure to toxic pollutants. To accomplish this a mathematical factor is used to reduce the lowest dose (concentration) that produces an unacceptable response (effect) to a "safer" acceptable level. This dose becomes the established PL. Safety factors are considered necessary because of the many uncertainties associated with extrapolation of animal data to humans (i.e., variations in responses between species and between individuals of the same species) and because of the vast number of factors that influence human susceptibility to a toxic effect of a given substance.

In the US, safety factors are typically built into each standard

established. The margin of safety between the lowest effective dose and a proposed TLV expressed mathematically is, TLV = lowest effective dose/safety factor. The safety factor depends upon the nature of the response produced by the lowest effective dose; that is, if a response to a chemical substance is localized and reversible, it is assigned a low safety factor, and, if the response is non-reversible or severe, it is given a high safety factor. "The ACGIH TLV's have been estimated to extend between 0.2 and 10". (Smyth, 1959). The safety factors used in establishing PL's for pollutants in food and drinking water range from 10 to 1000 depending on the available data on studies of the pollutant in question (Calabrese, 1978)

In the USSR several approaches have been proposed for the derivation of safety factors. According to Izmerov (1973) PL's should be provided with a safety factor of 30% in all cases. This means that if a presumed threshold is found, the next level tested is 30% lower. If there is no pollutant-induced activity at that level, the experimentation can stop, with that final concentration becoming the PL. Calabrese (1978) stated that although this may seem like a very samll safety factor as compared to the factors of 10 and 100 in the US it must be recalled that "the Soviets are trying to prevent the occurrence of the most sensitive indicator of exposure and not necessarily the truly pathogenic response" (Calabrese, 1978). However, the accepted approach for the use of safety factors in the USSR presently, is reported by Kagan (1975) in which the use of mathematical derivations based on set formulae are used. These set formulae take into account the quantitative correlations between toxic effects, chemical structure, and physiochemical properties of the toxicants considered. Magnuson et al. (1964) presented the following formula that represents the theoretical basis on which the safety factor in the Soviet

Union is often based and the relationship of the safety factor to the MAC.

$MAC = LIM_{CH}/K$

K = a safety factor

Derivation of K

$$K = a \frac{\frac{LIM_{AC}}{LIM_{CH}} \quad \frac{C_{20^0}}{LC - 50}}{\frac{LC - 50}{LIM_{AC}}}$$

$$= a \frac{\left|\frac{LIM_{AC}}{}\right|^2 \quad C_{20^0}}{(LC\text{-}50)^2 \times LIM_{CH}}$$

LIM_{AC} = lowest single dose giving an effect

LIM_{CH} = lowest repeated dose giving an effect

C_{20^0} = vapor concentration at 20^0

(LC - 50) = 2 hr LC - 50

a = 1 for vapor? for nonvolatile materials

LIM_{AC}/LIM_{CH} = zone of chronic action

C_{20^0} /(LC - 50) = coefficient of possible inhalation exposure

$(LC - 50)/LIM_{AC}$ = zone of acute action

Magnuson et al.(1964) reported that the use of this formula with respect to safety factor derivation may provide considerable insight in explaining some of the striking differences between American and Soviet PL values, especially with regard to aromatic hydrocarbons and chlorinated hydrocarbons, which tend to have high volatility. Magnuson et al. (1964) thought that the use of vapor pressure in the derivation of MAC's is an erroneous approach for the following reason. Since the MAC is considered to be a level of an atmospheric concentration of a substance, "whether that concentration results from

a chemical of low volatility or of high volatility should not make a difference on the MAC" (Magnuson et al., 1964). The question of volatility is an important one with respect to engineering controls and in selecting appropriate materials, but it is not a factor per se in the development of toxicity.

Economic and Technical Feasibility versus Health

In establishing industrial health standards in the US, great consideration is given both economic and technical feasibility while in the USSR these considerations are not of any real significance. American scientists criticize the Soviets for not allowing for economic and technical feasibility in setting their extremely stringent PL's and the Soviet scientists criticize the US for placing too much emphasis on these considerations and not enough on the health of the worker in setting PL's.

Hatch (1972a) in admitting that the USSR approach provides a greater factor of safety for the worker, questions whether it is necessary to adopt such stringent standards. He agrees that protection of the health of exposed individuals is the first responsibility, and all other considerations are secondary. However:

> in an industrial society it is also important not to impose more restrictions than are needed to provide adequate health protection, since excessive controls can seriously restrict many operations and add greatly to the cost of manufacture. To establish permissible limits, therefore, it must be shown that the proposed limits of exposure are necessary and that they are sufficiently low (Hatch, 1972a).

Similarly, Magnuson (1965) stated:

> although I also recognize extremely low MAC values for highly toxic compounds, the excessive monitoring of their harmful action is a needless waste of human resources and it may interfere with the use of chemical substances and processes which themselves can be of enormous importance to progress in our social, economic and physical health.

Magnuson et al. (1964) after observing the application of Soviet methods and PL's stated that it was both economically and technically unfeasible to enforce the "unreasonable" low limits that were established and, based on observations in the field and discussion with Soviet scientists they believed that the PL's were not rigidly adhered to and that, in actuality, excursions above these values "within reasonable limits" are permitted (Magnuson et al., 1964)

In contrast, the Soviets are highly critical of many American toxicologists who have advocated a relaxation of activities aimed at securing healthy working conditions based on economic, technical, and other difficulties. Sanockij (1975) in a sharp criticism of those who would sacrifice health for economics and industrial progress stated:

> it is impossible to count on significant progress towards health without providing the fundamental conditions for preserving and strenghtening it, and without removing toxic substances from the environment; this is one of the principal factors that influence health at a time when chemistry is rapidly developing (Sanockij, 1975).

In the USSR, the priority of medical arguments over all others, including "technical feasibility", has long been the rule when PL's are established. Under conditions of rapid technological progress:

> difficulties that appear insurmountable today may easily be overcome tomorrow. Scientifically based permissible levels are bound to stimulate the introduction of new engineering techniques with the aim of creating healthier technological processes and equipment (Letevet, 1962 quoted by Sanockij, 1975).

Sanockij gives several examples of fruitful cooperation between Soviet engineers and physicians. For example, the reduction of the concentrations of dust, associated with the risk of silicosis, down to the established MAC level in many mines in the USSR that was formerly regarded as "not technically feasible".

The Soviets also find fault with the definition of TLV adopted by

the ACGIH. The definition reads as follows:

> Threshold limit values refer to airborne concentrations of substances and represent conditions under which it is believed that nearly all workers may be repeatedly exposed day after day without adverse effect. Because of wide variation in individual susceptibility, however, a small percentage of workers may experience discomfort from some substances at concentrations at or below the threshold limit; a smaller percentage may be effected more seriously by aggravation of a pre-existing condition or by development of an occupational illness (ACGIH, 1976b).

According to Sanockij (1975) this definition deliberately accepts unfavorable effects and even occupational diseases in individual workers. He states that economic considerations are the basis for this acceptance of disease and further points out that the American use of "emergency limits" and "short term" exposure limits" for many hazardous agents are "theoretical justification of unsatisfactory working conditions" in an effort to cut costs for good engineering controls (Sanockij, 1975).

Adoption of Standards

The formal mechanisms for the actual adoption of a standard are quite different between the US and USSR and may be a major factor in the large divergences in the PL's. The monolithic structure of the Soviet Union permits a degree of formal planning difficult to achieve under the US economy and system of government. The Soviet Ministry of Health is responsible for all facets in the setting and enforcement of PL values ranging from the toxicologic investigations in the laboratory to the supervision of exposures within industry. An official permanent commission regularly engaged in determining the MAC's recommends such values to the Ministry of Health. With the advice of the Institute of Industrial Hygiene and Occupational Diseases, these values are declared Soviet Standards and are published by the Ministry of Health (ILO, 1977). In contrast, the US standards are the result of diverse resources and

viewpoints including input from industry, labor unions, insurance carriers, research institutes, universities and professional and trade associations. The National Institute for Occupational Safety and Health (NIOSH) makes use of the information gathered from these various resources concerning experimental and epidemiological studies on the pollutant in question. In addition, these resources provide valuable information concerning economic and technical feasibility of the proposed PL. NIOSH submits this information including a review of the literature with respect to the pollutant to OSHA with a recommended standard. OSHA then creates an independent committee (outside of OSHA and NIOSH) made up of representatives from industry, labor and scientific organizations, to critically review the evidence supporting the proposed standard. The findings of this committee and those of NIOSH are then considered by OSHA and a decision is made whether to promulgate the proposed standard. From the many varying viewpoints of those involved in deciding whether a PL should be established at a particular level it is easy to understand the problem of setting lower standards in the US.

Other Differences

There are a number of other differences both in approaches taken by the US and USSR and also in implementation and enforcement of the established PL's. Table 6 lists most of these plus presents a summary of the previously mentioned differences. From the large number of differences listed it would appear that little hope is offered for future agreement of PL values between the US and USSR. However, it may be of some value to consider the changes in approaches and in PL values that have occurred in the past and to look at possibilities for future trends.

TABLE 6
DIFFERENCES IN APPROACHES TO STANDARD SETTING IN THE US AND USSR

(Based on Calabrese, 1978; Dinman, 1976a; Zielhuis, 1974; and Magnuson et al.1964)

U.S.A.	U.S.S.R.
A. Approaches to Setting Industrial Standards	
1. Philosophical concepts believed to be influenced by Descartes (dualism of body and mind).	1. Philosophical concepts founded on Lenin and Pavlovian principles of unity of body and mind.
2. Changes at the cellular and organ level are possibly isolated effects within the organism; there is more or less a direct pathway from uptake to organ, not necessarily mediated through the CNS.	2. A deviation of organ functions is regarded as a reflection of total response of the organism mediated through the nervous system (Pavlov concept).
3. Dose-response studies start at high levels at which demonstrable ill effects occur and works downwards, using increasingly sensitive measures of various disturbances.	3. Dose-response studies start at low levels and works upwards from an assumed initial standard of normality in the test organism, using highly sensitive measures of behavioral or other forms of response.
4. Emphasis on cell and organ pathology, biochemistry.	4. Emphasis on behavior and central nervous system testing.
5. Standards permit minor physiologic adaptive changes to be developed.	5. MAC[1] will not permit the development of any disease or deviation from normal.
6. Economic and technologic feasibility are important considerations in the development of US standards. (Note: OSHA is is required to perform "inflationary impact statements" for proposed standards).	6. Standards should be based entirely on health and not technological and economic feasibility.
7. Values are time-weighted averages and in some instances "ceiling limit values".	7. Concentrations are maximum values that are not to be exceeded at any time. Similar to US "ceiling limit values".

Table 6 (continued)

U.S.A.	U.S.S.R.
8. With the exception of carcinogens in the workplace, goals of zero exposure have not been seriously discussed.	8. Goal to be achieved is a zero level of exposure.
9. Concentrations will protect nearly all workers, not occasional hypersensitive or hypersusceptible individuals.	9. Concentrations will protect all workers, even the most sensitive individuals.
10. Much reliance on epidemiologic studies in human beings.	10. Relatively more reliance on controlled animal experimentation.
11. Safety factors incorporated into each standard are based, mostly on the nature of the response produced by the lowest effective dose.	11. Safety factors (reserve coefficients) calculated for each MAC and take into account the quantitative correlations between toxic effects, chemical structure, and physiochemical properties of the toxicants considered.
12. Approach is pragmatic, following flexible rules.	12. Approach is dogmatic, following strict rules.
B. Manner of Obtaining Experimental and Clinical Data for Setting Limits	
1. Highly varied sources--government, industry, universities, etc.	1. Highly structured--the only data available are those for which the government has planned.
2. Inefficient exchange of scientific information.	2. More efficient exchange of scientific data.
C. Formal Mechanism for the Actual Adoption of a Standard	
1. As a result of the OSHA[2] Act of 1972, --NIOSH is charged to develop a review of the literature with respect to a pollutant and any relevant information from other sources.	1. Government selects scientific review committee; they recommend a standard to the Ministry of Health; if Ministry agrees, they institute a standard. Decision of standard

Table 6 (continued)

	U.S.A.	U.S.S.R.
1.	--NIOSH[3] submits this to OSHA with a recommended standard. --OSHA then creates an independent committee (outside of OSHA and NIOSH) to critically review the evidence supporting the proposed standard. Following the review process, OSHA decides whether to promulgate a standard. The decision of standard adopted is influenced by various authorities in addition to scientists.	1. adopted is solely made by scientists.
D.	Enforcement of Standards	
1.	OSHA is responsible for the enforcement of US industrial health standards.	1. Function of: --inspectors of Ministry of Health (medical public health training). --inspectors from the All Union Councils (engineers). --inspectors from local trade union committee.

1. MAC - Maximum Allowable Concentrations
2. OSHA - Occupational Safety and Health Administration
3. NIOSH - National Institute of Occupational Safety and Health

CHAPTER IV
TRENDS

There are varying opinions among scientists in different parts of the world as to whether the various differences mentioned in the previous section will ever be completely resolved with the subsequent development of nearly identical PL's for both the US and USSR. A review of the literature has indicated the majority opinion is that there is an extremely low probability of this ideal situation ever occurring. Three major differences which are unlikely to ever change are the basis for this opinion: (1) differences in types of effects investigated; (2) differences in the interpretation of the meaning of the effects found and; (3) differences in the formal mechanism for adoption of the PL's. However, although the opinion that the ideal of complete resolvement of differences and identical PL's is improbable, many of these scientists agree that some of the differences are being diminished and that there is hope for better agreement both in approaches taken and values established between the two countries.

US Changes and Trends

Historically speaking, Americans have always assumed the presence of a healthy environment. It was only adverse health effects such as death or disease that caused action to be taken. Our whole environmental movement, including occupational health, is clearly one of reaction to adverse health effects. Elkins (1961) noted that many of our occupational health standards have been based on primitive criteria ranging from death to changes in body or organ weight. Hatch (1972a) concurred with this perspective and stated that in the US the overwhelming thrust in standard setting has been an adoption of lower and lower values as a result of the development of

increasingly more sensitive indicators of preclinical, physiologic, biochemical, and other indices of functional disturbances. The case of the carcinogen vinyl chloride demonstrates how industrial health standards employed in the US have markedly changed as a result of biomedical studies indicating more enhanced risk than previously thought. In 1962 the ACGIH adopted a 500 ppm TLV for vinyl chloride and in 1974, based on studies that showed carcinogenicity, OSHA proposed a standard of "no dectable level". Later that same year, due to the development of more sensitive indicators, OSHA issued the standard requiring the reduction of exposures to 1 ppm/8hr TWA with 5 ppm Max and 0.5 ppm action level (Calabrese, 1978). Another example is the development of the present OSHA standard of 1 ppm for benzene from a 1946 ACGIH standard of 100 ppm also based on carcinogenicity studies. It is interesting to note that in 1961, the Soviet MAC for Benzene was 6 ppm and is presently 1 ppm and for vinyl chloride it was 12 ppm in 1961 and remained the same until 1979 when it was withdrawn from the USSR list of standards (Vigliani, 1976 and Fairchild, 1979).

The above examples are just a very small representation of the many PL's that have been lowered in the US during the past 20 years because of the development of newer more sensitive techniques to detect both clinical and pre-clinical adverse effects. There is reason to believe that this trend will continue and as more sensitive techniques are developed additional established PL's will decrease. However, recent changes in efforts to control toxic substances (see below) indicate that this system is changing and that there are those who feel there are too many new chemicals being produced that can cause adverse health effects to risk the wait for the development of more sensitive techniques to detect them.

The passage in 1976 of the Toxic Substances Control Act (TSCA), which demands pretesting of all new chemicals planned to be used in interstate commerce seems to be a major shift within the US to adopt the overall orientation of the Soviets with respect to the development of accurate toxicologic dose-response relationships on the basis of well defined animal (and other) testing. The adoption of pretesting procedures offers what has been widely referred to as a front end control process. Such a perspective, of necessity, leans heavily on the development of a broad variety of toxicologic testing procedures, employed prior to the granting of manufacturing approval of the substance in question so that adequate safety testing can be completed before any significant human exposure occurs. As previously mentioned, well before TSCA, Soviet law required that all new chemical substances be subjected to compulsory preliminary toxicological evaluation prior to production or use in industry (Sanockij, 1975). Consequently, many future industrial standards in the US may be based entirely on toxicologic studies with follow up epidemiologic studies serving to validate the previous toxicologic test results and interpretations. Epidemiologic studies, as previously noted, have played a vital role in the derivation of many US standards and undoubtedly will continue to be an important force in the development of future standards. However, Calabrese (1978) points out that the "long-term role of epidemiologic studies in standard derivation seems to be that of applying the "fine tuning" to the conclusions derived from previous toxicologic studies". Furthermore, in some cases, the epidemiologic studies will undoubtedly uncover diseases that slipped through the predictive testing procedures of the toxicologic methods. From this it would appear that testing in the US will probably be more like that of the USSR rather than the other way around. In addition, there may

even be an increased usage of some Soviet toxicologic testing methods.

Although most American toxicologists are of the opinion that the Soviets are excessively preoccupied with neurophysiologic studies and there use as indicators of disease in setting standards, several have found some merit in these studies. Magnuson et al. (1964) found the quality and quantity of the Soviet work on the effects of drugs and chemicals on the central nervous system to be exceptionally high and:

> the careful mapping of the precise sites of action of drugs acting on the central nervous system and the feedback of that information to programs synthesizing new drugs is an activity which should have long-range scientific benefits in pharmacology, neurology and psychiatry (Magnuson et al., 1964).

Likewise, Calabrese (1978) stated:

> from a scientific perspective, it would appear that the Soviet emphasis exploring the effects of altered CNS function (via pollutant activity) on health is clearly an area in which Western scientists could learn from their Soviet counterparts. A cursory knowledge of psychosomatic illness, including the effects of stress on health, suggests that environmental scientists should closely examine this area.

Calabrese (1978) explained further that Western developments in this area may in fact result in greater areas of agreement between American and Soviet approaches to standard setting. However, "unless pollutant-induced CNS instability can be directly tied to the induction of some disease process, it is likely that such data will not play a significant role in standard derivation in the US" (Calabrese, 1978). Recent expansion of US research into pollutant-induced central nervous system responses (Dinman, 1973) indicates an effort to explore some of the Soviet claims.

Another method that has received considerable attention by a number of Western scientists is the approach adopted by the Soviets in the derivation of health standards for carcinogens. Whereas considerable controversy has

been engendered in the US concerning the development of an acceptable approach to deriving "safe" levels for carcinogens, the USSR has acted very quickly. It was the first country in the world to establish the PL for 3, 4-benzo {a} pyrene (Fomenko, 1975). The principle on which the Soviets based their approach to carcinogens is that the latent period varies inversely with the dosage.

The original research supporting the present standard for 3, 4-benzo {a} pyrene was conducted, according to Calabrese (1978), by Yanysheva and Antomonov in 1976. They used groups of rats exposed to a variety of doses by using intratracheal administration. The results indicated that the number of rats with tumors decreased as the benzo {a} pyrene dose was lowered. Furthermore, there was an inverse relationship of latent period and dose; that is, the lower the dose, the longer it would take for a tumor to develop.

> Yanysheva and Antomonov mathematically estimated the appearance of the initial lung tumor after administration of the different total doses of benzo {a} pyrene. At 0.05 mg the first lung tumor is projected to occur toward the very end of the animal's life span. Lower doses (0.02 - 0.002 mg) are projected to initiate lung tumor development progressively beyond the animal's natural life span (Calabrese, 1978).

On the assumption that humans may respond in similar fashion to these rats with respect to dose-time-effect relationships, a dose of 0.02 mg was recommended as the permissible dose used in the dose-concentration formula. Thus the Soviets have chosen to select a PL that, in theory, will cause an effect (i.e., cancer) after the expected normal lifetime of the individual (Sidorenko and Pinigin, 1975).

Calabrese (1978) points out that although the data on the benzo {a} pyrene carcinogenesis in rats is quite impressive with respect to developing a dose-time-effect relationship, it is highly debated whether data derived

from rat experiments should be directly extrapolated to humans. However, "a number of Western environmental/occupational toxicologists and epidemiologists (Jones and Grendon; Thomas and Busick; Druckery and; Enterline) seem to support the approach adopted by the Soviets" (Calabrese, 1978).

Additionally, there is an apparent increased recognition of Soviet toxicologic studies by the US as evidenced by the numerous references to Soviet experimental results as found in the ACGIH "Documentation of the Threshold Limit Values for Substances in Workroom Air" (ACGIH, 1976a). These references have been most numerous during the past 10 years and several TLVs for various chemical substances have been changed (lowered) partially based on Soviet findings. Some examples of these chemical substances are epsilon caprolactum, chlorodifluoromethane, formamide, manganese clyclopentadienyl tricarbonyl, vinyl chloride and benzene. These are just a few of the many chemical substances that have had stricter standards placed on them by ACGIH and OSHA, and this apparent trend for lower and lower PL's that are more towards the Soviet PL values should be considered more closely.

In the past, vast differences between Soviet and American standards were known but apparently did not exist for all types of industrial pollutants. Elkins (1961) compared American and Soviet standards in the early 1960s when it was generally recognized that the standards of these two countries were often at variance with each other; that is, the Soviet standards are, in general, considerably lower than those of the US. Elkins noted that standards (i.e., based on 1960 standards) for irritant gases and vapors in the US and the USSR were in generally close agreement, with several notable exceptions such as acetaldehyde and ethylene oxide, for which the ACGIH-recommended TLVs were 67 (200 vs 3 ppm) and 80 (50 vs 0.6 ppm) times higher than Soviet standards respectively. In contrast to the irritants, the Soviet standards

for both hydrocarbon solvents and especially the chlorinated hydrocarbons are often considerably lower than those standards proposed by the ACGIH. Furthermore, there is also reasonably good agreement between the Soviet and ACGIH values for both the organic dusts and fumes as well as the inorganic dusts and fumes. Once again, there are exceptions such as chlordane, dimeton, and lindane for organics and lead, manganese, metallic-mercury and tellurium for inorganics (Elkins, 1961).

Calabrese (1978) compared the values reported by Elkins (1961) to the 1976 ACGIH values for some irritants and found that there were a considerable number of changes in the ACGIH-TLV's. These changes almost invariably resulted in lowered levels (i.e., stricter standards). Soviet 1976 standards for several irritants were also compared to those of 1961 and these also reflect several reductions (e.g., ammonia and dimethyl formamide) in MAC levels. However, in several instances (e.g., hydrogen fluoride and sulfur dioxide) there have been increases. Calabrese (1978) concluded that the extend of the differences between the US and USSR standards have not markedly diminished, although for some irritants, there has been considerably closer agreement in PL's.

While Calabrese (1978) and Elkins (1961) used only ACGIH values for comparison to the Soviet MAC's, a more recent comparison using the lowest US recommended values reveals a greater convergence of PL's. Table 7 is a comparison of the findings of Elkins (1961) to those of a comparison of the 1977-78 Soviet and American standards for several industrial pollutants. In this comparison, however, US values are those of either OSHA, ACGIH or NIOSH depending on which is the lowest PL reported. It must be noted, however, the NIOSH and ACGIH values reported are only recommendations and do not represent the official US standards although in most cases these values will

TABLE 7
COMPARISON OF SOVIET AND ACGIH INDUSTRIAL
STANDARDS (1961) TO SOVIET AND US STANDARDS (1978)

Substance	1961 Values[1] USSR	ACGIH	fv [3]	1978 Values[2] USSR	USA	fv
A. Irritant Vapors (in ppm)						
Acetaldehyde	3.0	200	67	3.0	(A) 100	33
Acetic acid	2.0	10	5	2.0	10	5
Acrolein	0.3	0.5	1.7	0.3	0.1	0.33
Ammonia	30.0	100	3	15	(A) 25	1.7
Dimethyl formamide	3.0	20	7	3.0	10	3
Ethylene oxide	0.6	50	83	0.5	50	100
Formaldehyde	0.8	5	6	0.3	(A) 2	6
Furfural	2.5	5	2	2.5	5	2
Hydrochloric acid	7.0	5	0.7	3.6	5	1.4
Hydrogen fluoride	0.6	3	5	0.8	3	3.8
Iodine	0.1	0.1	1	0.1	0.1	1
Ozone	0.05	0.1	2	0.05	0.1	2
Nitrogen dioxide	2.0	5	2.5	2.0	5	2.5
Phosgene	0.1	1	10	0.1	0.1	1
Sulfur dioxide	3.0	5	1.7	4.0	(N) 2.0	0.5
Toluene diisocyanate	0.07	0.1	1.4	0.07	(N) 0.005	.07

Table 7 (continued)

Substance	1961 Values USSR	ACGIH	fv	1978 Values USSR	USA	fv
Butylamine	3.0	5.0	1.7	3.0	5.0	1.7
Chlorine	0.3	1	3	0.3	1	3
Diethylamine	10.0	25	2.5	10.0	25	2.5
B. Hydrocarbon Solvents (in ppm)						
Benzene	6	25	4	2	1	0.5
Butadiene	45	1000	22	45	1000	22
Coal tar naptha	25	200	8	25	100	4
Styrene	12	100	8	1	100	100
Toluene	13	200	15	13	(N) 100	8
Turpentine	55	100	2	55	100	2
Xylene	12	200	17	12	100	7
C. Chlorinated Hydrocarbon Solvents (in ppm)						
Carbon tetra-chloride	3	25	8	3	10	3
Chloro-benzene	11	75	7	11	75	7
Chloroprene	0.6	25	42	0.6	25	42
Dichloro-benzene	3	50	17	3	50	17
Dichloro-ethylene	13	200	15	13	200	15
Ethylene dichloride	2.5	100	40	2.5	(N) 5	2
Methylene chloride	14	500	36	14	(N) 75	5

Table 7 (continued)

Substance	1961 Values USSR	ACGIH	fv	1978 Values USSR	USA	fv
Trichloro-ethylene	9	200	22	2	100	50
Vinyl chloride	12	500	42	8	1	0.13
D. Miscellaneous Solvents and Organic Vapors (in ppm)						
Amyl acetate	20	200	10	20	100	5
Cyclohex-anone	2.5	100	40	2.5	50	20
Dioxane	3	100	30	3	(A) 50	17
Butyl alcohol	65	100	1.5	3	(A) 50	17
Methyl alcohol	40	200	5	4	200	50
Propyl alcohol	80	400	5	4	200	50
Aniline	0.8	5	6	0.03	5	167
Butyl acetate	40	200	5	42	150	4
Carbon disulfide	3	20	7	3	(N) 1	0.33
Nitro-propane	8	50	6	8	25	3
Pyridine	1.5	10	7	1.5	5	3
E. Miscellaneous Gases and Vapors (in ppm)						
Acrylo-nite	0.25	10	40	0.25	(N) 4	16

Table 7 (continued)

Standards	1961 Values USSR	ACGIH	fv	1978 Values USSR	USA	fv
Carbon monoxide	17	100	6	17	(N) 35	2
Hydrazine	0.1	1	10	0.1	(A) 0.1	1
Hydrogen sulfide	7	20	3	7	(A) 10	1.4
Phosphine	0.07	0.05	0.7	0.7	0.3	4
F. Organic Dusts and Fumes (in Mg/M^3)						
Chlordane	0.01	2	100	0.01	0.5	50
Demeton	0.02	0.2	10	0.02	(A) 0.1	5
Parathion	0.05	0.1	2	0.05	(N) 0.05	1
Trinitro-toluene	1	1.5	1.5	1	(A) 0.5	0.5
G. Inorganic Dusts, Fumes and Mists (in Mg/M^3)						
Cadmium	0.1	0.1	1	0.1	(A) 0.05	0.5
Chromic acid, chromates	0.1	0.1	1	0.01	(N) .001	0.1
Lead	0.01	0.2	20	0.01	0.05	5
Mercury-metallic	0.01	0.1	10	0.01	(N) 0.05	5
Molybdenum-insoluble	6	15	2.5	6	(A)10	1.7
Selenium oxide	0.1	0.1	1	0.1	0.2	2
Titanium oxide	10	15	1.5	10	(A)10	1

Table 7 (continued)

Footnotes: 1. 1961 Values:
USSR and ACGIH values from Elkins, H. B. (1961) Maximum Acceptable Concentrations. Arch Environmental Health 2: 45-49

2. 1978 Values:
USSR and USA values obtained from ILO (1977) Occupational Exposure Limits for Airborne Toxic Substances. Geneva, International Labour Office. Occupational Safety and Health Series, No. 37

USA values also obtained from US Department of Health Education and Welfare (1978) NIOSH/OSHA Pocket Guide to Chemical Hazards. US Department of Labor, Occupational Safety and Health Administration. (September 1978)

All 1978 USA values are official OSHA standards unless otherwise indicated as follows: (A)= ACGIH recommended standard
(N)= NIOSH recommended standard

3. fv - factor of variance = US PL/USSR PL (permissible level).

probably be officially adopted in the future. However, if in fact some of the NIOSH or ACGIH recommended standards are not adopted, they still represent a trend in American scientists' desire for stricter standards.

Similarly, Fairchild (1979) reported the apparent trend toward American and Soviet PL agreement. He noted the lowering of approximately 60 US TLV's during the past 12 or 13 years and made special mention of the even lower NIOSH future recommendations that may lead eventually to greater agreement in PL values between the two countries.

Soviet Changes

Although it appears that the trend has been, and probably will continue to be for a lowering of US standards, thus more closely approximating those of the Soviet Union as well as for some of the US approaches to deriving those standards to become more like those of the USSR, it is not totally a one-sided shift. The Soviets have also made some changes in their opinions and approaches to standard derivation, and some of these are similar to those of the US. However, although some of these changes are indicative of better agreement between approaches to standard setting in the two countries, they do not indicate that Soviet standards in the future will elevate, i.e., become less strict.

As previously mentioned in Chapter III, the Soviets have not regarded epidemiologic studies as significant in the standard derivation process. However, there seems to be a changing concept in the USSR for these types of studies with an apparent increase in the use of industrial experience and epidemiologic studies. Volkova (1975) states that PL's of toxic substances that have been established as a result of animal experiments are only tentative values and must be corrected to make them applicable to man. As a result, the process of establishing these limits can be divided

into the following two stages (Volkova, 1975): "(1) experimental research on animals; and (2) clinical hygiene studies on conditions of work and the health and functional state of workers exposed to the given substance". Volkova points out that in the USSR, many MAC's for chemical compounds have been corrected in this second stage. Epidemiologic studies including morbidity data of workers who have been exposed to various pollutants have been extremely important in revising MAC's for several chemical toxicants (e.g., styrene, formaldehyde, hexavalent chromium, benzene) that were considered at a "safe" level based on initial toxicological investigations. Moreover, epidemiologic studies are incorporated into the multistage process for the compulsory investigation of new chemical substances before they can be used in industry. The epidemiologic (statistical) investigations are used in the final stage of the process when the substance is being introduced into industry and agriculture. These studies provide not only a "safe" level MAC, but also therapeutic and prophylactic measures; methods of early diagnosis; first aid and; treatment (Sanockij 1975).

In addition to a greater use of epidemiologic studies, there is apparently a change in the Soviet concept of adverse health effects. Zielhuis (1974) is of the opinion that the Soviets are beginning to abandon the extremely stringent criteria that any effect, whatsoever, including those considered to be normal compensation responses of the body, are considered adverse. He offers as an example of this apparent relaxation of this stringent concept the new definition of MAC proposed by Sanockij (1975):

> The maximum allowable concentration of a chemical compound in the environment is the concentration that, by its action on the human body periodically or throughout life, directly or indirectly via ecological systems and also through possible economic losses, will not cause the development of physical or mental diseases (including latent and temporarily compensated conditions) or changes in the state of health that go beyond the limits of adaptive physiological

> responses, detectable by modern methods of investigation either immediately or in the long term, in this or subsequent generations.

Zielhuis (1974) contends that the Soviets seem to consider a limited change within the limits of physiological fluctuation may not always be unacceptable. "Nowadays there appears to exist a trend to take more into account the normal variability of physiological parameters, inducted by various stimuli, including the occupational stimuli" (Zielhuis, 1974).

WHO Opinion

The most optimistic point of view as regards the possibility of PL agreement between the US and USSR is that taken by the World Health Organization (WHO, 1977). They state that although there are several underlying scientific and philosophical differences, the basic objectives in establishing permissible levels are now very similar in both countries. They emphasize that the ultimate goal in both countries is to prevent disease and maintain the health of the workers throughout their life time.

> It is anticipated that future official standards originating from the USA, the USSR, and other parts of the world may be more in agreement, and international organizations such as WHO and ILO will be more able to make international recommendations based on a broad consensus among health scientists (WHO, 1977).

CHAPTER V
CONCLUSIONS

The US and USSR are the leading countries in the world for establishing occupational standards and thus greatly influence the standards that are adopted by other industrial nations as well as industrially developing countries. Therefore, it is reasonable for WHO to attempt to promote closer agreement between the industrial standards of these two countries in an effort to develop a list of internationally accepted PL's for various toxic substances. However, major differences in philosophical concepts between the US and USSR have led to the adoption of different approaches to the standard derivation process which consequently has resulted in vast divergences in the PL values recommended.

Recently, there have been apparent changes in some of the approaches and criteria used by the US and USSR in establishing industrial standards with the majority of changes being made by the US in adopting approaches similar to those used in the USSR. In addition, there have been a number of changes in US recommended industrial standards for several pollutants that have indicated a trend toward lower PL values that are in more agreement with the Soviet PL values. However, because of the differences in basic concepts and requirements of the two approaches for distinguishing between a state of health and potential ill health, it is not likely that total agreement will be achieved on PL's of exposure. Furthermore, these differences in concepts of health and potential ill health are not likely to be resolved because there is no clear-cut borderline between optimal health and health impairment resulting from exposure to a toxic substance. Likewise, there is no clear-cut answer as to whether the US PL values or

the USSR PL values are more appropriate and/or correct. The answer remains a matter of opinion. The only real validation of adopted PL values must come from the health records of the exposed workers and not from theoretical considerations and arbitrary definitions of good health. This seems logical since even the "most correct" PL will do little if unachievable or is not carried out for one reason or another.

Despite differences in philosophical concepts and approaches to deriving industrial standards, the US and USSR have the same goal -- to maintain an optimum state of health in the working population. Both countries have excellent occupational health programs and have made tremendous progress in the development of various new equipment and techniques for medical evaluation, toxicological testing and industrial monitoring. Through the efforts of WHO and ILO there has been an increasing exchange of information between experts from these countries which has led to closer agreement on several approaches to setting standards and on various methods and techniques in toxicological and epidemiological studies. Although there are many unresolved differences, the changes and trends mentioned in Chapter IV of this paper indicate that there is reason to believe that future official standards originating from the US and USSR may be more in agreement, and that international recommendations can be made for acceptable PL values for many industrial pollutants.

BIBLIOGRAPHY

ACGIH (1976a) Documentation of TLV's for Workroom Air, (3rd Edition). American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio.

ACGIH (1976b) Threshold Limit Values for 1976. American Conference of Governmental Industrial Hygienists, Cincinnati, Ohio.

Calabrese, E. J. (1978) Methodological Approaches to Deriving Environmental and Occupational Health Standards. New York, N. Y.: John Wiley and Sons, Inc.

Dinman, B. D. (1972) "Non-Concept" of "no-threshold": Chemicals in the Environment. Science 175: 495-497.

Dinman, B. D. (1973) Personal Communication to Prof. Dr. R. L. Zielhuis (cited in Zielhuis, 1974).

Dinman, B. D. (1976a) Development of Workplace Environment Standards in Foreign Countries. Pt. 1 - Historical Perspectives; Criteria of Response in the USSR. Journal of Occupational Medicine 18(6): 409-417.

Dinman, B. D. (1976b) Development of Workplace Environment Standards in Foreign Countries. Pt. 2 - Concepts of Higher Nervous Function in the U.S.S.R. Journal of Occupational Medicine 18(7): 477-484.

Dinman, B. D. (1976c) Development of Workplace Environment Standards in Foreign Countries. Pt. 3 - Procedures for the Development of MAC Values in U.S.S.R. Journal of Occupational Medicine 18(8): 550-560.

Elkins, H. B. (1961) Maximum Acceptable Concentrations. Arch Environ Health 2: 45-49.

Fairchild, E. J. (1979) International Perspectives in Occupational Health Standards and PL's. Speech material presented at The American Industrial Hygiene Conference, May 31, 1979. Chicago, Il. (in press).

Fomenko, V. N. (1975) Long-term Effects of Exposure to Toxic Substances. WHO. Methods Used in the U.S.S.R. for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 75-85.

Hatch, T. F. (1972a) Permissible Levels of Exposure to Hazardous Agents in Industry. Journal of Occupational Medicine 14: 134-137.

Hatch, T. F. (1972b) The Role of Permissible Limits for Hazardous Airborne Substances in the Working Environment in the Prevention of Occupational Disease. Bulletin of World Health Organization. 1972, 47: 151-159.

ILO (1970) Joint ILO-WHO Committee on Occupational Health: Permissible Levels of Toxic Substances in the Working Environment. Geneva, International Labour Organization. Occupational Safety and Health series. No. 20 (1970).

ILO (1977) Occupational Exposure Limits for Airborne Toxic Substances. Geneva, International Labour Organization. Occupational Safety and Health Series, No. 37 (1977).

Izmerov, N. F. (1973) Principles Underlying the Establishment of Air Quality Standards in the USSR. In: Control of Air Pollution in the USSR., pp 42-60, 129-132. Geneva: WHO.

Kagan, Ju. S. (1975) Accumulation and Adaptation Processes in the Action of Chemical Agents in the Environment. WHO. Methods used in the USSR for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec 12-19, 1972. World Health Organization: Geneva,

Switzerland. 1975: 56-74.

Ljublina, E. I. and Filov, V. A. (1975) Chemical Structure, Physical and Chemical Properties and Biological Activity. WHO. Methods used in the USSR for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 19-41.

Magnuson, H. J., Fassett, D. W., Geralde, H. W., Rowe, V. K., Smyth, H. F., Jr., and Stokinger, H. E. (1964) Industrial Toxicology in the Soviet Union - theoretical and applied. Industrial Hygienists Association Journal, 25: 185-197.

Magnuson, H. J. (1965) Soviet and American Standards for Industrial Health. Arch Environmental Health 10: 542-545.

Pavlenko, S. M. (1975) Methods for the Study of the Central Nervous System in Toxicological Tests. Methods used in USSR for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 86-108.

Prague, Symposium (1959) Proceedings of the International Symposium on MAC's of Toxic Substances in Industry. International Union of Pure and Applied Chemistry. Prague, 1959, Butterworths, London, 1961 as cited in (Dinman, 1976a).

Rjazanov, V. A. (1965) Criteria and Methods for Establishing Maximum Permissible Concentrations of Air Pollution. Bulletin of World Health Organization. 32: 389-398.

Sanockij, I. V. (1975) Investigation of New Substances: Permissible Limits and Threshold of Harmful Action. WHO. Methods Used in the USSR

for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 9-18.

Sidorenko, G. I., and Pinigin, M. A. (1975) Establishment of Safe Levels of Chemicals in Communal Hygiene: Methodological Approaches. WHO. Methods Used in the USSR for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 126-138.

Smyth, H. F., Jr. (1959) The Toxicologic Basis for TLV's: 1. Experience with TLV's based upon animal data. AIHA Journal. 20: 341-345.

Smyth, H. F., Jr. (1976) Food and Cosmetic Toxicol., 5:51.

Stockinger, H. E. (1969) Introduction to Threshold Limit Values for 1969. American Conference of Governmental Industrial Hygienists. Chicago, 1969.

Stockinger, H. E. (1972) Concepts of Thresholds in Standards Setting. Arch Environmental Health 25: 153-157.

U. S. Department of Health, Education and Welfare (1978) NIOSH/OSHA Pocket Guide to Chemical Hazards. U. S. Department of Labor, Occupational Safety and Health Administration. (September 1978).

Vigliani, E. C. (1976) Working document prepared for the WHO Meeting of Experts, Geneva, Switzerland, 24-30. August 1976.

Volkova, Z. A. (1975) Use of Data on Human Health and Environmental Conditions. WHO. Methods used in the USSR for Establishing Biologically Safe Levels of Toxic Substances. Meeting - Moscow, USSR, Dec. 12-19, 1972. World Health Organization: Geneva, Switzerland. 1975: 160-168.

World Health Organization (1969) Permissible Levels of Occupational Exposure to Airborne Toxic Substances. Sixth report of the Joint ILO/WHO Committee on Occupational Health. World Health Organization: Geneva, 1969. Techn. Rep. Ser. No. 415.

World Health Organization (1977) Methods Used in Establishing Permissible Levels in Occupational Exposure to Harmful Agents. Report of a WHO Expert Committee with the Participation of ILO. Techn. Rep. Ser. No. 601. World Health Organization: Geneva, 1977.

Zielhuis, R. L. (1974) Permissible Limits for Occupational Exposure to Toxic Agents: A Discussion on Differences in Approach Between U.S. and USSR. Int. Arch. Arbeitsmed. 33: 1-13.

VITA

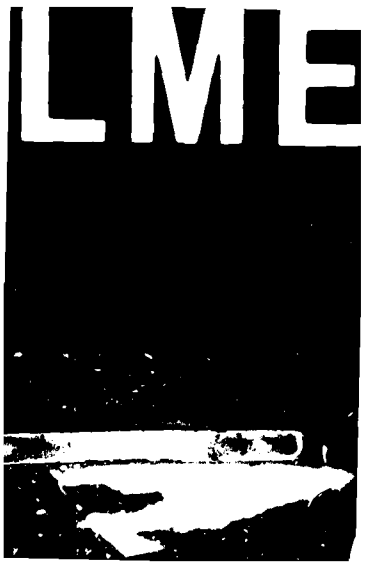
Robert John Brauchler was born in New York City, New York, on December 22, 1944, the son of George Frederick Brauchler and Helen Stimmel Brauchler. After completing his work at Sewanhaka High School, Floral Park, New York, in 1962, he entered Nassau Community College, Garden City, New York and majored in biology. With the Viet Nam conflict at its peak, in 1965 he postponed his academic endeavors and enlisted in the U.S. Navy where he completed training as a Hospital Corpsman and Operating Room Technician. During 1967-1968 he served in Viet Nam with the U.S. Marine Corps as a combat medic and after completing his full military commitment, was honorably discharged from the service in 1969. Upon returning to Nassau Community College he earned the degree of Associate in Applied Science in nursing, being selected for the Dean's List both years and passed the New York State Licensing Examination for Registered Nurses in 1971. While working as an operating room nurse at Nassau County Medical Center, East Meadow, New York, he attended the State University of New York at Stony Brook and received the degree of Bachelor of Science in Biology in 1973. The following year he accepted a commission in the U.S. Air Force Nurse Corps.

His professional activities in the Air Force began at Columbus AFB, Mississippi, where he became an operating room supervisor and infection control nurse. In 1976 he completed special training in infectious disease control techniques at the Center for Disease Control in Atlanta, Georgia and became a member of the Association for Practioners in Infection Control. He was decorated for Meritorious Service for his outstanding performance of du-

ties at Columbus AFB and in 1978 was transferred to Travis AFB, California. While there, he served as the infection control coordinator of David Grant USAF Medical Center and was involved with several nosocomial infection research projects. In September, 1979 he was accepted for training as an environmental health nurse and was transferred to the University of Texas Health Science Center, School of Public Health, San Antonio, Texas in order to complete requirements for a master's degree in Public Health.

He is married to Audrey A. Brauchler and has three children ranging in age from 16 to 7.

Permanent address: 5 Clinton St., Elmont, New York 11003


LME